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[REDACTED] EXAMINER

ROSE, SHEP K

ART UNIT	PAPER NUMBER
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1614

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action SummaryApplication No.
10/035320Applicant(s)
B A R A B O C A K et al

Examiner

SHEP Rose

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—**Period for Reply**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on _____.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 1 1; 453 O.G. 213.**

Disposition of Claims

1624

- Claim(s) _____ is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) _____ is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). 2
- Notice of Reference(s) Cited, PTO-892
- Notice of Draftsperson's Patent Drawing Review, PTO-948

 Interview Summary, PTO-413 Notice of Informal Patent Application, PTO-152 Other _____**Office Action Summary**

This application is a continuation of allowed Application Serial No. 09/453,383, filed December 2, 1999, with allowed claims 28 to 32 to an antiplaque chewing gum in pellet form comprising a water insoluble portion, a water soluble portion, and a coating on the pellet which comprises an emulsifier, triclosan and a surfactant, with about 1mg to about 6 mg of triclosan included in each piece of gum, and a method for reducing plaque by the step of orally applying said chewing gum to the mouth, raising an issue of obviousness-type double patenting of claim 6 to 14, 16 to 22 herein, to the same chewing gum, (claim 17 and 18 imply a chewing gum should be recited in claim 15), also, of claims 1 to 5 and 15 generic thereto.

The claims require, in addition to ~~triclosan~~ both an emulsifier and a surfactant. The surfactant is cetylpyridinium chloride in claims 2, 9 and 19. the term of these claims "emulsifier" encompasses species other than set forth in the specification on page 6, lines 27-28. "Emulsifiers may include lecithin, glyceryl monostearate, or other mono and diglycerides. . ." (There are also softeners), and a typical chewing gum has both (as see page 7, lines 1 to 14).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-32 of copending Application No. 09/453,383. Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1614

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The legal basis for an inherency rejection, one that can properly be made under 35 U.S.C. § 102/103, is set forth in MPEP § 2112-2112.02 citing In re Fitzgerald et al., 205 USPQ 594. When the reference discloses all the limitations of a claim except a property or function, whether or not the reference inherently possesses properties or renders obvious the claimed invention, there is basis for shifting the burden of proof to applicant. Also, MPEP § 2183-2184, when the reference teaches all the claim limitations except a claimed element, an examiner is not certain whether the element disclosed in the reference is an equivalent to the claimed element and therefore anticipated, or whether the prior art element is an obvious variant of the claimed element.

Here, the Examiner will rely on extrinsic evidence (Merck Index) to establish with certainty that that Libin (I) U.S. 5,236,699A, 17 August 1993, a reference introduced into the record by applicants on their PTO-1449 IDS, is an anticipation, under 35 U.S.C. § 102, of claims 1, 2, 4, 5, 15, 19 and 23 because 2 (two) of the surfactants employed with Libin's enhanced anti-plaque combination of (a) Triclosan and (b) cetylpyridinium chloride, are described by Merck Index as emulsifiers, (c) Tween 20 surfactant, and (d) Pluronic L64 surfactant.

Claims 1, 2, 4, 5, 15, 19 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Libin (I) U.S. 5,236,699A, 17 August 1993, who describes an enhanced activity anti-plaque aqueous alcoholic vehicle for mouthwash, comprised of: (a) Triclosan, a water insoluble anti-plaque agent, 0.01 to 0.05%; (b) cetylpyridinium chloride, a water soluble antiplaque agent (it's a cationic surfactant as well), 0.020% to 0.030%; (c) Tween 20, a triclosan solubilizer, 0.5 to 2%, a polysorbate pharmaceutical emulsifier and surfactant dispersing agent, (according to Merck Index entry 7742); (d) Pluronic L64, 10%, as a foaming agent, which is an emulsifier, (according to Merck Index, entry 7722), said combined agent coaction of (a) and (b) to afford highly effective enhanced antibacterial activity against dental plaque, (e) water, 67%; and (f) alcohol, 18%.

Libin fully anticipated claims 1, 2, 4, 5, 15, 19 and 23 (mouthwash) under 35 U.S.C. § 102, since these claims either recite no percentage concentration levels for any of the components, and the surfactant percentages of claim 4 are described, as noted above.

Claims 3, 4, 20 and 21 differ from Libin (I), in requiring 3% (a) Triclosan instead of 0.05%, and in requiring, while the chewing gum claims 6-14 and 16-18 are not described, nor is the toothpaste or gel of claim 24.

Applicants' attorney made some interesting remarks concerning Anderson et al. U.S. 5,487,902A, 30 January 1996, and Hill U.S. 5,380,530A, 1 October 1995, both references introduced into the record by applicants and cited on their PTO-1449 IDS, respectfully submitting that the Hill reference does not teach or suggest the use of an emulsifier, but rather a variety of surfactants which can be used within emulsions to function as a surfactant, and that, moreover, the Anderson reference, which admittedly uses a variety of "SOLUBILIZERS", to solubilize chewing gum base resin, ". . . does not teach or suggest the desirability of using nonionic surfactants as an emulsifier, . . .", it being admitted in remarks that Hill specifically coats chewing gum with an emulsion containing a surfactant or an emulsifier, it being further argued that neither Hill nor Anderson discloses the use of a nonionic surfactant as an emulsifier, and that clearly the Hill and Anderson references do not teach the use of a nonionic surfactant as an emulsifier.

The USPTO Examiner's position here is that they do not have to state that their surfactants are emulsifiers, if extrinsic evidence (Merck Index) establishes that such encompassed species of nonionic surfactants to be used are emulsifiers. Moreover, the term "surfactant" in claims 1, 6, 11, 14, 15 and 21 is not coincident in scope with "NONIONIC SURFACTANT" as argued.

Claims 1-7, 9-11, 13, 15-17 and 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson et al., U.S. 5,487,902A, 30 January 1996, who describe a chewing gum with active agents to be chewed for 2 to 10 minutes, said chewing gums including: (a) Triclosan (column 9, line 24; 0.1 to 10% at column 10, line 26 and 0.01 to 30% at column 12, line 53; (b) cetylpyridinium chloride at column 8, lines 54-55; and "AT LEAST ONE" and "A COMBINATION OF SEVERAL" at column 6, lines 21-22 and claim 12; (c) solubilizers-surfactants (column 5, line 57 to column 6, line 24, 1% to 10% at column 10, lines 56-57, column 12, line 55 and claim 4; (d) emulsifying active agent solubilizing agents, column 7, lines 8-26, 0 to 12%.

Anderson et al. Anticipates claims 1-7, 9-11, 13, 15-17, and 19-21 but does not specify a weight of 1 mg to 6 mg of Triclosan per piece of gum as in claims 12 and 22, and do not state to chew the gum three times per day as in claim 18, and do not describe a mouthwash toothpaste or gel as in claims 23 and 24.

Applicants' counsel's parent case remarks have inadvertently overlooked the terms "AT LEAST ONE" and "A COMBINATION OF SEVERAL" (c) solubilizer surfactants as well as the (d) emulsifiers employed by Anderson in chewing gum base with (a) Triclosan and (b) cetylpyridinium chloride, neither recited to be in a coating on the gum, or inside the chewing gum base center itself, while claim 14 "IN PART" unfortunately does not recite or require that 100% of the Triclosan is in the pellet coating on the pellet center, there being "NO TRICLOSAN WHATSOEVER" in applicants' specified chewing gum base or gum pellet center as a careful review of the specification will establish to anyone's satisfaction.

Claims 1, 2, 5-7, 9, 13-16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hill U.S. 5,380,530A, 10 January 1995, taken with Libin (I) (details as noted above), it being within the level of skill of the art to replace a single surfactant-emulsifier with a combination of two of ^hem, as described by Libin (I), (details as noted above), the Examiner relying on Merck Index extrinsic evidence to establish that claim encompassed surfactants of Hill are known as emulsifiers as well.

Hill, according to applicants' counsel's parent case remarks does not anticipate these claims under 35 U.S.C. § 102 because a single surfactant and emulsifier are employed with Triclosan to coat the chewing gum, but to interchange a combination of a surfactant and an emulsifier to attain the same goal is clearly prima facie obvious 35 U.S.C. § 103.

Hill describes an anti-plaque coating on chewing gum comprising (a) an emulsifying agent (column 10, lines 51-55); (b) Triclosan (column 9, line 58, column 15, line 26, Example 17, Table II, 0.2 to 1.0%, and claim 2; and (c) cetyl pyridinium chloride (column 15, line 30 and claim 2; and (d) a surfactant, claim 9, column 10, lines 11-50; and (e) chewing gum plasticizer softening agents which happen to be applicants' "emulsifiers" according to the recitals of this specification at page 6, lines 22-28 and Example 2 page 10: Hydroxylated lecithin in the Example, lecithin, glycerol monostearate, or other mono or diglycerides, Hill describing acetylated monoglycerol triacetate, glycerol diacetate, and lecithin, 0.4 to 0.6% at column 19, line 65 to column 20, line 11.

Hill (details as noted above) renders obvious (35 U.S.C. § 103) claims 1, 2, 5-7, 9, 13-16, and 19 the rejection being made under 35 U.S.C. § 103, but differs from, and does not suggest claims 3, 10, 20 and 22 in the percentage of Triclosan (1% versus 3%), and differs from claims 4, 11 and 21 in not specifying the percentage of surfactant in the anti-plaque Triclosan chewing gum coating.

Hill does not describe the mouthwash or toothpaste or gel as in claims 23 and 24.

Moreover, the term "an emulsifier" in claims 1, 6, 14 and 15 is not co-extensive in scope with applicants' described and enabled species of emulsifiers (page 6, lines 27-28: ". . . Emulsifiers may include lecithin, glycerol monostearate, or other mono-and di-glycerides . . .", hydroxylated lecithin in the pellet gum coating of Example 2, page 10. moreover, the only species of surfactant therein with the Triclosan being "CETYLPYRIDINIUM CHLORIDE" or "CPC", a cationic surfactant, page 11, lines 25 and 26 adding ". . . However, other ionic and nonionic surfactants may also be employed in the pellet gum coating . . ." clearly, this is an understanding by applicants that nonionic surfactants may be described herein as surfactants and in Merck Index they are emulsifiers as well.

It is observed that the pellet gum center example has no Triclosan, no emulsifier, and no surfactant.

It is further observed that 100% of the Triclosan is in the pellet gum coating.

Yet, claim 14, even if read in light of the disclosure, contains the unfortunate recitation of "—IN Part—" implying that some of the Triclosan, surfactant and emulsifier

is in the pellet gum center, and claims 6 and 13 given their broadest reasonable interpretation in failing to recite that while there is a water soluble portion including an emulsifier, Triclosan and surfactant that it must be in a coating on the chewing gum but is (not even in part) ever inside the chewing gum base center herein.

Since it is the policy of the USPTO to give pending claims their broadest reasonable construction, claims 6 and 13 can be reasonably interpreted to read on prior art placing anti-plaque actives not only in the coating on the gum, but also in the gum base center itself.

Giving claims 6 and 13 the reasonable interpretation that the Triclosan anti-plaque agent is placed inside the chewing gum center base and in claim 14 the reasonable interpretation merely also can be placed –in part—inside or absorbed while –in part—some can be placed in a pellet coating on the pellet center, as distinguished from being absorbed on the chewing gum but not in a coating, the Examiner would select from the material relevant and important prior art submitted into the record by applicants and cited by them on the IDS PTO-1449 prior art described by applicants' attorney as "A PLETHORA" (?), only Reiner U.S. 5,711,961 (January 1998) and Reed et al U.S. 5,248,508 (9/93) a very modest plethora will be employed because Reed et al. describe and claim the precise palatinate (hydrogenated isomaltalose) sweetener in the pellet coating on a pellet gum center.

Reiner et al U.S. 5,711,961 (1/98) describes chewing gum tablets (or "pellets", as elected), wherein the chewing gum base tablets have active agents absorbed onto their surface, in sugary microgranules with additive active agents, or used alone, and the

sugary microgranules can be coated with delayed release coatings. At column 3, Example 2 describes 0.010 milligrams of Triclosan in 1.4 grams of gum, while Example 3, describes 1 milligram of cetylpyridinium chloride in 1.5 grams of gum.

Reiner et al (column 4, lines 46-55) mixes active ingredients known to be unpalatable into the gum with sugary microgranules. Applicants, according to the recitals of the specification, admit that cetylpyridinium chloride and Triclosan are well known to be extremely bitter tasting, and following Reiner et al. they would be placed inside the chewing gum base center. While applicants herein have 100% of the Triclosan and cetylpyridinium chloride in the pellet outer coatings, and 0% of each inside their chewing gum base center, claims 6, 13 and 14 are clearly not commensurate in scope with applicants' disclosed enabled and described invention, but the broadest reasonable interpretation of these claims metes and bounds must be given.

Claim 1 does not recite or even require (and as elected) that –said anti-plaque emulsion comprise a coating of the pellet chewing gum in pellet form--.

Claim 1 does not define the emulsion as defined in the specification on page 6, lines 22-28 and Example 2 on page 5 as said emulsifier being selected from the Markush group consisting of –hydroxylated lecithin, lecithin, glycerol monostearate, other mono-and diglycerides--. The term “surfactant” in claim 1 clearly encompasses surfactants which function inherently and have been described in the prior art as emulsifiers.

Since it is the policy of the USPTO to give pending claims their broadest reasonable interpretation, as noted above.

In an attempt to advance the prosecution of this application to a more timely issue, the Examiner will point out the well known fact, as a matter of common knowledge in the art, that the two (2) surfactants of LIBIN (I) function as emulsifiers according to Merck Index. The claims that had been rejected under 35 U.S.C. §n 102/103 on Libin alone on a theory of inherency , based on this well known fact MPEP § 706.02 (a), 707.07 (f) can properly be rejected either on 35 U.S.C. § 102 or on 35 U.S.C. § 103.

Libin (II) and Libin (III) in the parent case had been withdrawn as cumulative in nature to Libin (I), (they describe the gel of claim 24).

Once the inherency of Libin (I) is established in the record, it becomes clear that this reference, in fact, applies to the claims that it was solely applied to, namely claims 1, 2, 4, 5, 15, 19 and 23 herein.

The patent case election therein was of the pellet chewing gum, recited only in claims 13 and 14. in claim 14, which depends on claim 6, the water-soluble portion of the Triclosan surfactant and an emulsifier is not in fact the enabled coating on the chewing gum, or on the chewing gum pellet. While claim 13 recites the gum as in pellet form, and it is admitted prior art, and admitted in parent case. Remarks, and as set

forth as such in this specification that conventionally, chewing gum contains an emulsifier. Claims 6 and 13 require no more than the triclosan and a surfactant be inside a chewing gum base with its conventional chewing gum emulsifier. Claim 14, contains the unfortunate recitation of in part, reciting that the emulsifier, triclosan, and surfactant, define in part a coating of the pellet.

A careful review of the specification reveals that fact the 100% of the triclosan is in the pellet chewing gum coating on the pellet chewing gum center, and that there is no Triclosan whatsoever in the chewing gum center itself.

Claims 6, 9, 12-14, 19 and 22 are object^{ed} to for failure to recite that the anti-plaque triclosan and cetylpyridinium chloride, an emulsifier composition is in an outer pellet on the Chewing gum pellet center, said chewing gum pellet coating containing Triclosan and cetylpyridinium chloride having objectionable bitterness at effective levels of use, said chewing gum pellet coating and center pellet being provided with sufficient levels of sweeteners to be acceptable and pleasant to chew--.

The parent case remarks and arguments by applicants' attorney (who has not been qualified as an expert) are not considered to be the opinion of an expert, see In re Schulze 145 USPQ 716"... Argument of counsel cannot take the place of objective evidence ...". They certainly reveal a lack of recognition that claims encompassed surfactants function as emulsifiers. There is no Rule 132 Declaration of any expert by

applicants who are considered to be skilled in the art to buttress or to support the argument, which is unsubstantiated. The following arguments have been made in the remarks:

“LIBIN” does not describe the use of an emulsifier …, “… to overcome the emulsifier element deficiency in Libin …” In this regard, Libin does not disclose an emulsifier…” “… Neither Hill nor Anderson discloses the use of a nonionic surfactant as an emulsifier …”; “… Clearly the Hill and Anderson references do not teach the use of a nonionic surfactant as an emulsifier …”, “Indeed Hill discloses a variety of surfactants but not that such surfactants may also function as an emulsifier”. “Thus combining the teaching of Libin with that of Hill would fail to arrive at applicants’ claimed invention because the required emulsifier element would be missing”.

The Examiner properly relies on Merck Index as extrinsic evidence showing that those of ordinary skill in that art know that the nonionic Tween and Pluronic surfactants of Libin, Hill and Anderson function as emulsifiers. See MPEP § 2131.01 (d) and MPEP § 2112-2113 for case law on inherency. See: Atlas Powder versus Ireco, 51 USPQ 2d 1943.

Applicant’s attention is directed to legal decisions, binding on USPTO Board of Appeals, holding to be inherent and not patentable, inoculating healthy plants with a known plant inoculants, heretofore employed in the prior art to protect them against phytopathogenic fungi. Novitski discovered that the known plant inoculants would also protect them against root dwelling plant pathogenic nematodes, a discovery neither

known nor appreciated. Nevertheless, the step of inoculating plants with the same inoculants necessarily and inherently protects them against nematodes.

Atlas Powder versus Ireco, 51 USPQ 2d 1943, (Fed. Cir.-1999), holds that the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not precluding a finding of anticipation. Whether or not an element is inherent in the prior art, is a fact question. Inherency is not necessarily coterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition does not render the old composition patentably new to the discoverer. The fact that the prior art taught away from the claim is, in fact, only "a showing that the prior art did not recognize the inherent function. This lack of contemporary understanding did not defeat the showing of inherency.

The discovery by applicants and their attorney who did not previously appreciate or otherwise did not recognize the inherent emulsifier characteristics or function of the claim encompassed surfactants of Libin, Hill and Anderson employed by them with Triclosan and cetylpyridinium chloride does not render their old compositions patentably new upon discovery of this inherent property of the surfactant ingredient contained in the prior art.

The Examiner has authority to require by way of a Rule 132 expert Declaration the applicant to prove that the subject matter shown in the prior art does not possess

the emulsifier characteristics relied upon. In re Schreiber 44 USPQ 2d 1421. Merck Index establishes that they do so possess this property.

Indication of patentability case made in the parent case of claims 12 and 22 if made dependent on claim 14 provided that – in part – is deleted and the claim would be to a coating with sweetener as noted above of the pellet chewing gum.

Reed et al. U.S. 5,248,508 (9/93) describes and claims a hard coating of palatinate sugarless sweetener on pellet chewing gum, the elected species.

The technical problem encountered herein by applicants, and applicants' solution to the claimed problem as exemplified in the specification on pages 12 and 13 is that both cetylpyridinium chloride and Triclosan are bitter tasting and a gum with a coating comprising 5 milligrams cetylpyridinium chloride (Example 4) and a gum with a coating of 11 milligrams Triclosan (Example 5), upon chewing, had objectionable bitterness which would probably preclude regular use, while 3 milligrams of cetylpyridinium chloride in the center (Example 6) was palatable and while Example 3, 5 milligrams of Triclosan and 1 milligram cetylpyridinium chloride in the coating (inventive) was pleasant to chew, thereby increasing the likelihood of regular use.

Applicants were asked in the parent application if these admittedly bitter tasting Triclosan and admittedly bitter tasting cetylpyridinium chlorides of comparative Examples 4, 5 and 6, as well as Example 3 (inventive) as set forth on pages 12 and 13 of the specification contained any sweeteners in amounts sufficient to mask their bitter taste? It is noted that Example 2 on page 10 "pellet gum coating" in addition to

Triclosan and cetylpyridinium chloride contains 88% palatinate sweetener as well as encapsulated high intensity sweeteners, and an emulsifier, hydroxylated lecithin.

While page 4 line 31 states that "optionally emulsions can also contain sweeteners ... ", there is no indication in the description of Examples 3, 4, 5 and 6 on pages 12 and 13 whether or not any sweeteners were included with the bitter tasting cetylpyridinium chloride and chloride anti-plaque agents.

The motivation to combine Example 2 0.01 milligrams of Triclosan and Example 3 1 milligram of cetylpyridinium chloride of Reiner to have both outside as a coating and not inside in a chewing gum arises from Libin (I) who has pointed out to applicants, has two surfactants, both described in the prior art as emulsifiers according to Merck Index, namely Tween 20, a nonionic surfactant and an emulsifier according to Merck index, as well as Pluronic L64, another nonionic surfactant, one which is an emulsifier according to Merck Index.

This prior art obvious combination of Libin with Hill, Reed et al. and Reiner (as noted above) would not meet the 1 milligram to 6 milligram Triclosan limitations of claims 12 and 13 of the specification that both a pellet coating of 5 milligrams cetylpyridinium chloride and a pellet coating of 5 milligrams of Triclosan both had objectionable bitterness which could preclude regular use, and all elected chewing gum claims except for claims 12 and 22, are not only readable upon the lesser amounts of cetylpyridinium chloride and Triclosan taught for their combined anti-plaque benefit by Libin (I), but they are also readable upon the greater amounts of each stated by applicants to have objectionable bitterness which would probably preclude regular use.

Claims 1-5, 15, 19, 20 and 21 have been (as noted above) rejected under 35 U.S.C. § 102 on Libin, U.S. 5,236,699, who describes the anti-plaque benefits, same as herein, of "CPC", cetylpyridinium chloride, (same as herein); "T", Triclosan, same as herein, and "S", a surfactant solubilizer for the water insoluble "T" namely "Tween 20", a nonionic surfactant, one which is not explicitly described in Libin and Merck Index establishing it to be a surfactant that is known as an emulsifier.

According to the recitals of page 4 lines 8-15 herein, and anti-plaque emulsion is formed using "T" Triclosan and "S", a surfactant, and water, same as in Libin, who describes 0.01 to 0.05 level of "T" Triclosan of 3% to 30%, and 0.01 to 10% "S" surfactant. Herein, the surfactant is "CPC", 0.1 to 10%, according to page 2 lines 18 and 21-22 and can be a nonionic surfactant (page 11 lines 25-26) and the emulsifier, according to page 6 lines 27-28 and page 7 line 14 includes lecithin, glycerol monostearate, or other mono-and diglycerides, hydroxylated lecithin in Example 2 page 10 lines 12 and 22, but none of these claims recites or require that the emulsifier be any of these. These claims read on surfactants established in the record by Merck Index to function as emulsifiers.

Libin meets these claims since the Tweens are well known in the art to be nonionic surfactants derived from sorbitan esters, and are used as emulsifying agents in pharmaceuticals.

Hill U.S. 5,380,530 describes an anti-plaque emulsion coating for chewing gum comprising (see claim 2), various antimicrobials, Triclosan (column 15, line 26) Example 17 Table II, cetylpyridinium chloride (column 15, line 30) etc. and a surfactant-emulsifier

(claim 9, column 10 lines 1-55), and lecithin (column 16 line 12), as well as applicants' monoglyceride emulsifier, called plasticizer-softening agents in Hill, column 19 line 25 to column 20 line 11.

Anderson et al. U.S. 5,478,902 describes chewing gum with hydroxylated lecithin and/or mono- or diglyceride solubilizing emulsifiers (same as herein), cetylpyridinium chloride "CPC" (claim 12) and Triclosan "T" (same as herein) as well as Tween and other nonionic surfactant solubilizers, (same as herein), kindly note "at least one" and "a combination of several" at column 6 lines 21 and 22 as see: column 5 line 45; column 6 line 49; column 7 lines 8-15; column 8 lines 54-55 for the "CPC", column 9 line 29 for the "T".

Applicants have filed an IDS listing fifteen (15) U.S. patents considered by applicants to be material relevant and important to the issue of patentability of the elected species claims to pellet chewing gum as well as claims generic thereto which have also been examined.

Of these applicant cited prior art references, coated pellet chewing gums, as elected are described in the Reiner et al., Tyrpin et al., Yatka, and Reed et al. patents, while anti-plaque emulsions of Triclosan and/or cetylpyridinium chloride are described in the Libin and Hill patents and Anderson et al. describes both Triclosan and cetylpyridinium in chewing gum.

This application has a priority date of December 17, 1998, and 24 claims.

Claims 15-24 are drawn to processes for reducing plaque by orally applying to the mouth an emulsion of "T" Triclosan, and an emulsifier and a surfactant. The

composition is not necessarily a chewing gum in claim 15. It can also be a mouthwash (claim 23), or a toothpaste or gel (claim 24). The surfactant is not necessarily “CPC” cetylpyridinium chloride, except in claim 19.

Composition claims 1-14 do not recite or require the emulsifier, surfactant and Triclosan to be in the coating of a pellet of pellet form chewing gum except in claims 13 and 14, and chewing gum is only recited and required by claims 6-14, not by claims 1-5 which are drawn to any emulsion of Triclosan emulsifier and surfactant. “CPC” or cetylpyridinium chloride is required to be the surfactant only in claims 2 and 9. In claims 23 and 24 the emulsion is in a mouthwash or in a toothpaste or gel.

Libin (5,236,699, as noted above) inherently anticipates claims 1-5, 15, 19, 20 and 21 failing only to describe the Tween nonionic surfactant to be in fact an emulsifier.

Claims 6, 7, 9, 10, 11, 12, 16-18 and 22 require that Libin’s “T” and “CPC” anti-plaque combination is in chewing gum, any sort of chewing gum. None of these claims need be pellet chewing gum as recited in claim 13, which claim does not require any anti-plaque material to be “in part” in a coating on the pellet as recited in claim 14.

Claims 6, 7, 9, 10, 11, 12, 16-18 and 22 have been (as noted above) rejected under 35 U.S.C. § 103 (a) as being unpatentable over Libin 5,236,699 taken with Hill 5,380,530 (details as noted above), who provides anti-plaque “CPC” and/or “T” emulsion coatings on chewing gum. Libin motivates the selection of “T” and “CPC” for their combined anti-plaque benefits.

Claims 13 and 14 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Libin and Hill (details as noted above) taken with any one of each of the coated

pellet chewing gums of Reiner et al. (details as noted above) and Reed et al. U.S. 5,248,508 (details as noted above).

Hill motivates the provision of an anti-plaque emulsion coating of “T” and/or “CPC” on chewing gum, not explicitly stated to be in the form of pellet chewing gum. Libin motivates the selection of the combination of “t” and “CPC”, as well as a solubilizing surfactant, a Tween nonionic sorbitol ester well known in the art to be an emulsifier. Since none of the claims recite or require that the emulsifier be in fact hydroxylated lecithin as in Example 2 page 10, an emulsifier (page 6 lines 27 and 28: Emulsifier may include lecithin, glycerol monostearate or other mono or diglycerides” and page 7, line 14. It is prima facie obvious to place an anti-plaque emulsion coating in the coating at least in part on pellet chewing gum as in this applicant supplied references.

OBVIOUS COMBINATION CASE LAW

As stated in In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA-1980):

“... It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in Crockett, 126 USPQ 186, 188 (CCPA-1960), the idea of combining them flows logically from their having been individually taught in the prior art.

Likewise, see: In re Pinten, 173 USPQ 801, 803 (CCPA 1972); and In re Susi, 169 USPQ 423, 426 (CCPA-1971).

Claim 24 (to a gel) is rejected as *prima facie* obvious, under 35 U.S.C. 103 in view of either of Libin (II) U.S. 5855872 or Libin (III) U.S. 5945089 who add semi solid "gel" antiplaque formulations to the antiplaque mouthwash formulation of Libin (I) U.S. 5236699 (details as noted above) who describes antiplaque triclosan with cetylpyridinium chloride surfactant (same as applicants herein) along with components known (see Merck Index) to function as emulsifiers, namely: Tween 20 surfactant, and Pluronic L 64 surfactant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday from 7:30 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



SHEP K. ROSE
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April 11, 2002